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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,799	10/03/2001	Karl Andrew Garrill	PG4113US2	3583
23347	7590	01/25/2006	EXAMINER	
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			JOHNSON, JERROLD D	
			ART UNIT	PAPER NUMBER
			3728	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

JP

Office Action Summary

Application No.

09/971,799

Applicant(s)

GARRILL ET AL.

Examiner

Jerrold Johnson

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24,26-55,57-71 and 81-104 is/are pending in the application.
- 4a) Of the above claim(s) 125 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-24,26-55,57-71 and 81-104 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>21 Jun 2004, 18 Nov 2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I of a pouch with one or more moisture absorbing material, claims 1-24, 26-55, 57-71 and 81-104.

Species II of a pouch (flexible packaging) that prevents ingress of water vapor and particulate matter and permits egress of the propellant.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Michael Strickland on 12 January 2006 a provisional election was made without traverse to prosecute the invention of Species I, claims 1-24, 26-55, 57-71 and 81-104. Affirmation of this election must be made by applicant in replying to this Office action. Claim 125 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

Receipt of Terminal Disclaimers for 10/311,819 sent via facsimile on 12 January 2006 is acknowledged. Accordingly, this application now includes Terminal Disclaimers for this application as well as for 6,315,112; 6,390,291; 6,679,374 (10/071,674); 6,179,118; 6,119,853; and 09/599,274. There are no remaining Double Patenting rejections with respect to this Application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24, 26-55, 57-71 and 81-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (AAPA) in view of G. Williams and A Tcherevatchenkoff "Moisture Transport into CFC-Free MDIS (1998) and Shichman et al. US 5,322,161, Neteler US 6,531,197, Nikaido 5,300,858 and Examiner Official Notice.

Drug products of the types claimed disposed in MDI pressurized containers having an HFA-134a propellant are set forth as Applicant Admitted Prior Art (AAPA) in this and commonly owned patents/applications (6,315,112; 6,390,291; 6,679,374 (10/071,674); 10/311,819; 10/312,073; and 09/971,799).

G. Williams and A Tcherevatchenkoff "Moisture Transport into CFC-Free MDIS (1998) discloses the vulnerability of such MDI pressurized containers having an HFA-134a propellant to moisture intrusion.

Shichman discloses the use of metallic foil flexible pouches within which medical products vulnerable to moisture are packaged along with desiccant packages appearing to loosely held in the package so as to prohibit moisture damage to those products.

Shichman does not disclose that the metallic foil flexible pouch includes an additional moisture absorbing desiccant layer, particularly a layer of nylon in the form of a coating, lining film or mesh.

Nor does Shichman disclose the package being purged with nitrogen, being vacuum sealed. The Examiner takes Official Notice that such practices are the norm in the packaging of medical products such as this to avoid moisture contamination.

Re claims 42 and 43 Shichman also does not explicitly disclose the product by process limitations of vacuum deposition and sputtering.

The Examiner submits that product by process limitations are not limited by the process steps, but only by the structure they imply. The structure implied by these process steps is that of an aluminum foil layer, which is disclosed by Shichman.

Applicant in page 4, paragraph [0054] of 2004/0089561 (the published commonly owned co-pending application 10/311,819) discloses that the specific metal foil package having protective layers, heat seal layers, adhesive layer, etc. is a commercially available prior art product. This prior art disclosure does not set forth that the metal foil package includes a desiccant coating, lining, film or mesh, particularly one comprising nylon. It is not known if the product

Neteler discloses providing a metal foil pouch with a silica desiccant coating that may be impregnated (see abstract) or be adhesively laminated to the inner layer of the pouch.

And, Nikaido discloses a moisture proof package 117 to which a nylon desiccant 115 is disposed in the form of a coating, lining, film or mesh.

Accordingly, It would have been obvious to one of ordinary skill in the art to provide a flexible package of the type claimed with a first desiccant as disclosed by Shichman for the known prior art drug containing MDI an HFA-134a propellant so as prohibit moisture intrusion into the MDI.

It additionally would have been obvious to provide the flexible package with an additional second desiccant in the form of a nylon coating, lining, film or mesh as taught by Neteler and Nikaido to provide additional moisture protection to the MDI.

With respect to the foil layer thicknesses, one of ordinary skill in the art would know to vary such thicknesses so as to optimize the variable of moisture transmissibility.

With respect to the heat seal layer thicknesses, one of ordinary skill in the art would know to vary such thicknesses so as to optimize the variable of moisture transmissibility.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDJ 